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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/772,979

02/05/2004

Wayne A. Becker

1001.1526101

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08/10/2009

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MINNEAPOLIS, MN 55403-2420

EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

08/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/772,979

**Applicant(s)**

BECKER ET AL.

**Examiner**

Darwin P. Erez

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 4 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 5/7/09.

#### ***Claim Objections***

2. Claims 11, 26 and 41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

3. Claims 11 and 26 recite the limitation "the coil assembly includes a proximal taper", which is now similarly recited in amended independent claims 1 and 16.
4. Claim 41 recites the limitation "the coil assembly includes a first diameter section and a second diameter section having a diameter greater than the first diameter", which is now similarly recited in amended independent claim 31.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claim 1, 5-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,210,395 to Fleischhacker et al. and in view of US 6,143,013 to Samson et al.

Fleischhacker discloses a sheath in Fig. 24 capable of deploying an embolic filter, the sheath comprising: an elongate shaft **102** having a distal end and a lumen; a coil assembly including a first coil **M** defining a lumen, the first coil being wound in a first direction, a second coil **N** wound in a second direction, the second coil being disposed about an outer surface of the first coil (as seen in Fig. 1); wherein the coil assembly has a diameter that is larger than a diameter of the shaft; wherein the coil assembly is attached to the outer surface of the distal end of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil is attached to the distal end **206** of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil (shared lumen); wherein the first and second coils have circular cross section (as seen in Fig. 24); wherein the coil assembly is coated with a plastic polymer **108**; wherein the coil assembly is heat treated (col. 21, line 2). It is noted that the limitation for claim 13 is also being treated as a product-by-process claim. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited step, only to the structure implied by the step. Therefore, the process of heating the shaft to the coil assembly does not hold any patentable weight.

Fleischhacker discloses all the limitation of the claims, including the coil assembly having a first generally cylindrical section having a first inner diameter that is

greater than a diameter of the shaft (Fig. 24), but is silent with regards to a second generally cylindrical section having a second inner diameter greater than the first inner diameter, and a tapering between the first and second cylindrical sections.

However, Fig. 3 of Samson discloses a similar-type of reinforced catheter, wherein the catheter comprises a coil assembly **206**, and wherein the coil assembly includes a first and second cylindrical portions separated by a tapering portion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shaft and coil assembly of Fleischhacker to have a tapered portion because the shape of the shaft is merely dependent on the intended use of the device. It is well known in the art to have catheters with varying shapes and sizes. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the proximal end to have a tapering since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Note that coil assembly of Samson can be attached to a shaft 232 or 252, as shown in Figs. 7 and 8.

8. Claims 2-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischhacker et al. in view of Samson et al., as applied to claim 1 above, and in view of US 5,429,597 to DeMello et al.

As to claims 2-4, the modified device of Fleischhacker discloses all the limitations of the claims, except for the coils being multifilar. However, DeMello discloses a similar catheter having a shaft that is also reinforced with coils, wherein the coils are multifilar (col. 2, lines 36-41). Thus, the multifilar coil of DeMello is an

equivalent structure known in the art. Therefore, since the coil of Fleischhacker and the multifilar coil of DeMello were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the multifilar coil of DeMello for the coil of Fleischhacker.

As to claims 8-10, the modified device of Fleischhacker discloses all the limitations of the claims, except for the coil having a rectangular cross-section. Instead, Fleischhacker discloses a circular cross-section, as shown in Fig. 24. However, DeMello discloses a similar catheter comprising a shaft having a reinforced coil, wherein the coil is shown to have either a circular cross-section or a rectangular cross-section (col. 3, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the coil of Fleischhacker to have a rectangular cross-section because DeMello discloses that a coil having a circular cross-section or a rectangular cross-section are art recognized equivalents and would perform equally as well as a coil having circular cross-section. Furthermore, the applicant has not provided any criticality for the coil having a circular cross-section rather than a rectangular cross-section.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischhacker et al. in view of Samson et al., as applied to claim 1 above, and in view of US 6,165,163 to Chien et al.

The modified device of Fleischhacker discloses all the limitations of the claims except for the first and second coil being polymer coated wires. However, the use of polymer coated wires are well known in the art. For example, Chien discloses a similar-

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type of reinforced catheter, wherein the catheter comprises a coil assembly having a first coil and the second coil may be polymer coated (col. 14, lines 36-40). Chien discloses a coil assembly that is an equivalent structure known in the art. Therefore, because these two coil assembly arrangement (one without polymer coated wire and the other with polymer coated wire) were art recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the coil assembly of Chien for the coil assembly of Fleischhacker.

10. Claims 16, 20-22, 26-28, 31, 35-37, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,873,978 to Ginsburg and in view further view of US 6,210,395 to Fleischhacker et al. and US 6,143,013 to Samson et al.

Ginsburg discloses an embolic protection sheath comprising: an elongate shaft **12** having a distal end and a lumen (see Fig. 2); and an embolic protection device including an elongate wire **22** and a filter **14** attached thereto, wherein the wire is disposed at least in part of the shaft lumen (see Fig. 2 or 3).

Ginsburg is silent with regards to the elongate shaft and its distal end comprising a coil assembly; wherein the coil assembly includes a first coil and a second coil wound in opposite direction, the second coil being disposed about an outer surface of the first coil; wherein the coil assembly has a diameter that is larger than a diameter of the shaft; wherein the coil assembly is attached to the outer surface of the distal end of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil is attached to the distal end of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil; wherein the first and second coils have

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circular cross section; wherein the coil assembly is coated with a plastic polymer; and wherein the coil assembly is heat treated.

Fleischhacker discloses a sheath in Fig. 24 capable of deploying an embolic filter, the sheath comprising: an elongate shaft **102** having a distal end and a lumen; a coil assembly including a first coil **M** defining a lumen, the first coil being wound in a first direction, a second coil **N** wound in a second direction, the second coil being disposed about an outer surface of the first coil (as seen in Fig. 1); wherein the coil assembly has a diameter that is larger than a diameter of the shaft; wherein the coil assembly is attached to the outer surface of the distal end of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil is attached to the distal end **206** of the shaft, and the lumen of the shaft is in fluid communication with the lumen of the first coil (shared lumen); wherein the first and second coils have circular cross section (as seen in Fig. 24); wherein the coil assembly is coated with a plastic polymer **108**; wherein the coil assembly is heat treated (col. 21, line 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the reinforced catheter of Fleischhacker in the device of Ginsburg because the coils in the reinforced catheter of Fleischhacker will provide better resistance to kinking but still flexible enough to move through the vascular system.

The modified device of Ginsburg discloses all the limitation of the claims, including a coil assembly having a first generally cylindrical section having a first inner diameter that is greater than a diameter of the shaft (as shown in Fig. 24 of



Fleischhacker), but is silent with regards to a second generally cylindrical section having a second inner diameter greater than the first inner diameter, and a tapering between the first and second cylindrical sections.

However, Fig. 3 of Samson discloses a similar-type of reinforced catheter, wherein the catheter comprises a coil assembly **206**, and wherein the coil assembly includes a first and second cylindrical portions separated by a tapering portion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the shaft and coil assembly of Ginsburg/Fleischhacker to have a tapered portion because the shape of the shaft is merely dependent on the intended use of the device. It is well known in the art to have catheters with varying shapes and sizes. Furthermore, it would have been obvious to one having ordinary skill in the art to modify the proximal end to have a tapering since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Note that coil assembly of Samson can be attached to a shaft 232 or 252, as shown in Figs. 7 and 8.

11. Claims 17-19, 23-25, 32-34 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view Fleischhacker et al. and Samson et al., as applied to claims 16 and 31 above, and in view of US 5,429,597 to DeMello et al.

As to claims 17-19 and 32-34, the modified device of Ginsburg in view of Fleischhacker/Samson discloses all the limitations of the claims, except for the coils being multifilar. However, DeMello discloses a similar catheter having a shaft that is also reinforced with coils, wherein the coils are multifilar (col. 2, lines 36-41). Thus, the

multifilar coil of DeMello is an equivalent structure known in the art. Therefore, since the coil of Fleischhacker and the multifilar coil of DeMello were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the multifilar coil of DeMello for the coil of Fleischhacker.

As to claims 23-25 and 38-40, the modified device of Ginsburg in view of Fleischhacker/Samson discloses all the limitations of the claims, except for the coil having a rectangular cross-section. Instead, the coil assembly of Fleischhacker discloses a circular cross-section, as shown in Fig. 24. However, DeMello discloses a similar catheter comprising a shaft having a reinforced coil, wherein the coil is shown to have either a circular cross-section or a rectangular cross-section (col. 3, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the coil assembly of Ginsburg/Fleischhacker to have a rectangular cross-section because DeMello discloses that a coil having a circular cross-section or a rectangular cross-section are art recognized equivalents and would perform equally as well as a coil having circular cross-section. Furthermore, the applicant has not provided any criticality for the coil having a circular cross-section rather than a rectangular cross-section.

12. Claims 29, 30, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Fleischhacker et al. and Samson et al., as applied to claim 16 and 31 above, and in view of US 6,165,163 to Chien et al.

The modified device of Ginsburg in view Fleischhacker/Samson discloses all the limitations of the claims except for the first and second coil being polymer coated wires. However, the use of polymer coated wires are well known in the art. For example, Chien discloses a similar-type of reinforced catheter, wherein the catheter comprises a coil assembly having a first coil and the second coil may be polymer coated (col. 14, lines 36-40). Chien discloses a coil assembly that is an equivalent structure known in the art. Therefore, because these two coil assembly arrangement (one without polymer coated wire and the other with polymer coated wire) were art recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the coil assembly of Chien for the coil assembly of Fleischhacker.

### ***Response to Arguments***

13. Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773